

JAN 6 2006

1 of 2

KENDALL

15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
GiEntriport Single Lumen Adaptor

Section H – 510(K) Summary

**Date Summary
Was Prepared:**

December 5, 2005

**Submitter's
Information:**

The Kendall Company
Division of Tyco Healthcare Group, LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-8461

Contact:

Jim Welsh
Vice President, Regulatory Affairs
The Kendall Company
Division of Tyco Healthcare Group, LP
Telephone: 508-261-8532
Fax: 508-261-8461

**Device Trade
Name:**

GiEntriport with universal single lumen adaptor

**Device Common
Name:**

Tube, double lumen for intestinal decompression and/or intubation

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Kendall Next Generation Salem Sump, 510(k) number K040388, cleared on May 17th, 2004.
- Kendall E-Pump Enteral Feeding Sets, 510(k) number K040196, cleared on May 5th, 2004

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K053410

510(k) Premarket Notification
GiEntriport Single Lumen Adaptor

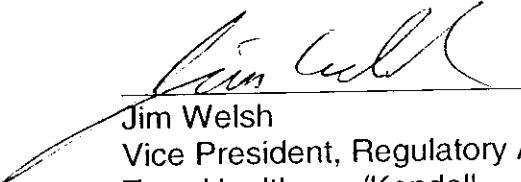
Section H – 510(K) Summary

Device Description: The GiEntriport with Universal Single Lumen Adaptor is a multiport connector/valve that can be connected to a Kendall Sump tube, or to a single lumen feeding tube.

Intended Use: The Kendall GiEntriport with Universal Single Lumen Adaptor is intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication.

Product Comparison: The proposed device has the same technological characteristics as the predicate devices. Both the proposed device and the predicate devices are intended to be used for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication. The construction of both the proposed and predicate devices is based upon a multifunction valve with external connection ports suitable for connection with commonly available devices such as vacuum adaptors, feeding sets, and irrigation syringes.

Nonclinical Testing: Engineering evaluation, and testing were conducted to demonstrate that the design of the proposed device was equivalent to the predicate devices, and/or met the industry accepted criteria for such devices, as defined in EN1615:2000.


Jim Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall

12-5-05
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Mr. James Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall
15 Hampshire Street
MANSFIELD MA 02048

Re: K053410
Trade/Device Name: GiEntriport with Universal Single Lumen Adaptor
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FEG
Dated: December 5, 2005
Received: December 7, 2005

Dear Mr. Welsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
GiEntriport Single Lumen Adaptor

Appendix 1

Indications for Use Statement

Device Name:

GiEntriport with Universal Single Lumen Adaptor

Indications for Use:

The device is intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication.

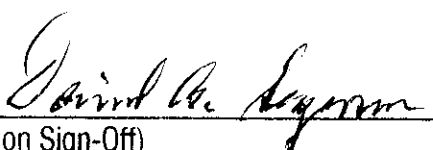
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐ _____


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Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K053410